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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,898	10/27/2000	Vito J. Palombella	MPI00- 133M	5304

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Intellectual Property Group
MILLENNIUM PHARMACEUTICALS INC
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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 02/24/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/697,898

Applicant(s)

PALOMBELLA ET AL.

Examiner

Elizabeth Slobodyansky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

The amendment filed December 3, 2002 (Paper No.13) canceling claims 1-26 and adding claims 27-52 has been entered.

Claims 27-52 are pending.

Election/Restriction

Applicant's election of species of SEQ ID NO:1 in Paper No.13 is acknowledged (Remarks, page 4). Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Objections

Claim 52 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 52 is drawn to a method for producing a polypeptide comprising a fragment. The scope of claim 33, from which claim 52 depends, does not include [a DNA encoding] a polypeptide comprising a fragment.

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Applicant is advised that should claim 51 be found allowable, claim 52 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The claims are drawn to a method for producing of the same polypeptide.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. The examples are : page 9, line 25; page 19, line 16; page 20, line 12, etc.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 27-30, 35-38 and 43-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way

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as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 27 (a, b), with dependent claims 28-30 and 35-38, is directed to a genus of DNA molecules with either SEQ ID NO:1 or cDNA insert of ATCC PTA-1836 or any DNA which is 90% or 95% identical to SEQ ID NO:1 or cDNA insert of ATCC PTA-1836 (claim 27(a, b) and dependent claims).

The specification does not contain any disclosure of the function of all DNA sequences that are 90% or 95% identical to SEQ ID NO:1 or PTA-1836. The genus of cDNAs that comprise these above cDNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. One skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claim 27(d) recites a nucleic acid molecule encoding a fragment comprising at least 500 amino acids of SEQ ID NO:2. Claim 47 recites a nucleic acid molecule encoding a fusion protein comprising at least 500 amino acids of a biologically active portion of SEQ ID NO:2. Claim 43 recites a nucleic acid molecule encoding a fusion

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protein comprising at least 500 amino acids of a biologically active portion of a sequence encoded by a DNA of claim 27, i.e. encoded by a DNA that is 90% or 95% identical to SEQ ID NO:1. There is no limitation on the structure and function of a nucleic acid or encoded polypeptide. Therefore, the claims are drawn to or depend from a enormous variable genus of DNAs encoding polypeptides comprising 500 amino acids having any function. The specification teaches the structure of only a single representative species of such nucleic acid molecules, i.e., that of SEQ ID NO:1. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than encoding at least 500 amino acids of SEQ ID NO:2 and fails to provide any structure: function correlation present in all members of the claimed genus. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 27-30, 35-38 and 43-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA encoding a fragment of SEQ ID NO: 2 consisting of at least 500 amino acids thereof, does not reasonably provide enablement for a a DNA encoding a polypeptide or fusion protein comprising at least 500 amino acids of SEQ ID NO: 2 wherein said polypeptide or

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fusion protein has no known activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are broader than the enablement provided by the disclosure with regard to the huge number of all possible derivatives having undefined structures and undisclosed functions.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Factors pertinent to this discussion include predictability of the art, guidance in the specification, breadth of claims, and the amount of experimentation that would be necessary to use the invention.

The specification does not support for the broad scope of the claims which encompass unlimited number of DNAs encoding polypeptides or fusion proteins of undefined structures and functions. The specification does not provide the guidance and in general, it is unpredictable at the current state of art how the polypeptide's

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structure relates to its function. Without knowing the function, it is impossible to know how to use a polypeptide/fusion protein and a DNA encoding thereof.

Therefore, one skilled in the art would require guidance as to how to use a DNA encoding a polypeptide/fusion protein of unknown function comprising at least 500 amino acids of SEQ ID NO:2 or a sequence that is 90% or 95% identical thereto in a manner reasonably correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

Claims 27-52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and /or use the invention.

Claims 27-52 recite the plasmid deposited with the ATCC as Accession Number PTA-1836.

The specification discloses that said plasmid was deposited on May 18, 2000 under the terms of the Budapest Treaty (paragraph bridging pages 9 and 10). However it is not apparent whether the deposit is readily available to the public. An affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his/her

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signature, and registration number, stating that the specific plasmids and/or strain(s) has/have been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. § 1.808.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27, 31 and 43-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 (a) and (b) are drawn to a nucleotide sequence which is at least 90% and 95%, respectively, identical to the cDNA insert of the plasmid deposited with the ATCC as Accession Number PTA-1836. Without knowing the sequence of said insert, it is impossible to know the metes and bounds of the sequences encompassed by the claim.

Claim 31 (line 5) and claims 51 and 52 are confusing as reciting "Accession Number PTA-1835".

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Claims 43-50 recite "biologically active portion". Said portion is defined by non-limiting examples in terms of both its structure and function rendering the metes and bounds of the term unascertainable (paragraph bridging pages 17 and 18).

Claim 43 is confusing as drawn to "a nucleic acid molecule encoding a fusion polypeptide comprising at least 500 contiguous amino acid residues of a biologically active portion of a polypeptide encoded by the isolate nucleic acid molecule of claim 27 and heterologous amino acid residues". The scope of polypeptides encoded by the nucleic acid molecule of claim 43 is different from the scope of polypeptides encoded by the nucleic acid molecule of claim 27. The nucleic acid molecule of claim 27(d) comprises a 500 amino acid fragment. It is unclear whether only part of claim 27 is included in the scope of claim 43. It is further unclear what is the difference between "fragment [that] comprises at least 500 contiguous amino acids" as in claim 27(d) and "polypeptide comprising at least 500 contiguous amino acid residues of a biologically active portion of a polypeptide" as in claim 43.

Claim 51 is confusing as drawn to a method for producing a polypeptide by culturing the host cell of claim 29. The scope of polypeptides encoded by the preamble of claim 51 is different from the scope of polypeptides encoded by DNAs contained in the host cell of claim 29.

Claim 52 is confusing as drawn to a method for producing a polypeptide by culturing the host cell of claim 33. The scope of polypeptides encoded by the preamble

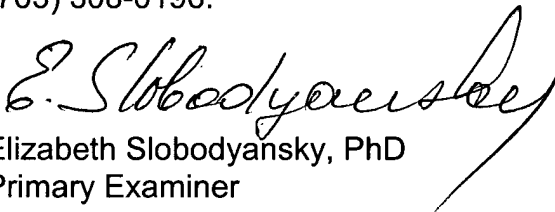
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of claim 52 is different from the scope of polypeptides encoded by DNAs contained in the host cell of claim 33. Furthermore, the scope of claim 33 does not include a DNA encoding a fragment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.



Elizabeth Slobodyansky, PhD
Primary Examiner

February 14, 2003